

REMARKS/ARGUMENTS

By this amendment, the title, independent claims 1, 5 and 16 and dependent claims 2, 4 and 23 are amended. Claims 1-7, 9, 11-19 and 21-24 are currently pending. In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 8, 10, 20 and 25-45 in a divisional application.

Claim Objections

Claim 23 has been amended to recite the radius of curvature in centimeters. No new matter is added, as a standard conversion factor was used. The specification has been similarly amended to state the radius of curvature in centimeters.

Claim Rejections – 35 USC §112

The rejection of claims 1-4 under 35 USC §112, second paragraph, is respectfully traversed. The Examiner indicated that “[t]he specification lacks definite language disclosing the connection means between the lever and the slide member, making claim 1 indefinite.” However, as the specification describes, no mechanical connection is necessary between these elements:

- “To effect reciprocal motion, the cam portion 90 of the lever 30 is received in a slot 92 of the slide member 82. There is no mechanical connection between the lever 30 and the slide member 82 in the first instrument 10.” (page 18, lines 8-10).
- “As shown in FIGS. 5-6 and 13, the slide member 82 has a drive surface 100 at the distal end of the slot 92 that is engaged by the cam 90 of the drive portion 88 of the lever 30 to cause the slide member 82 and distance references 78, 80 to reciprocate.” (page 18, line 20- page 19, line 1).

- “Assembly of the lever 30, 30A with the slide member 82 is simple in each of the embodiments 10, 12, 14. For the first two embodiments, 10, 12, when the slide member 82 is in position in the handle or the housing, the slot 92 in the slide member 82 is visible from the underside of the handle by looking through the lever slot 34. The lever 30, 30A can be assembled with the slide member 82 by inserting the drive portion 88, 88A of the lever 30, 30A through the entry slot 34 until the cam portion 90, 90A of the lever 30, 30A is received within the slot 92 of the slide member 82.” (page 29, lines 3-9).
- “For the modular embodiment 14 of FIGS. 16-18, prior to assembly, the slot 92 in the slide member 82 is visible through the entry 111 slot in the bottom of the housing 144 so the drive portion 88A of the lever 30A can be easily guided through this housing entry slot 111 and into the slide member slot 92 as the tool module 112 and actuator module 110 are pushed together. With the cam portion 90A of the lever 30A of the actuator module 110 aligned to be received in the slide member slot 92, the two modules 110, 112 can be pushed together until the housing 144 is supported by the concave support structure 118 and movement is constrained by the retaining structures at the proximal and distal ends 120, 122 of the handle.” (page 29, lines 13-21).
- “The surgeon can squeeze the trigger portion 86, 86A of the lever proximally causing the cam portion 90, 90A of the lever 30, 30A to pivot distally against the drive surface 100 of the slot 92 of the slide member 82, thereby causing the distance references 78, 80, 166, 168 or rods or tangs 180, 182 to move distally.” (page 30, lines 12-16).

In addition, FIGS. 5-6, 8, 18 illustrate the cam portion of the lever received within the slot of the slide member and engaging the drive surface of the slide member without being connected together.

Accordingly, the specification provides adequate written description of the relationship between the lever and the slide member to support claims 1-4: as described and illustrated, the drive portion of the lever is received in the slot and engages the drive surface of the slide member but there is no mechanical connection between the lever and the slide member.

Claim Rejections – 35 USC §102

The rejection of claims 16-19 under 35 USC §102(b) as being anticipated by Shutt et al. (5507772) is respectfully traversed.

First, if element 142 is considered the housing in the Shutt et al. reference, then it is difficult to discern what element could comprise the discrete hollow elongate support member, since element 142 appears to extend the substantially the entire length of the device illustrated in FIG. 11; there does not appear to be any elongate support element that has a proximal end received within element 142. With no housing and discrete hollow elongate support member, it does not appear that Shutt et al. discloses any connection between elements between the proximal end of a housing and the proximal end of a discrete hollow elongate support member. Therefore, independent claim 16 and its dependent claims 17-19 are patentable over Shutt et al.

Claim Rejections – 35 USC §103

Claims 1-4

The rejection of claims 1-4 under 35 USC §103(a) as being unpatentable over Lucey et al. in view of Shutt et al. is respectfully traversed. Slot 94 of Lucey et al. is part of a flexible region 90 that is located “slightly proximally to the distal end of inner tube 34 and positioned to lie within the bend region 20 of stationary tube 14. Flexible region 90 is integrally formed to be continuous with the adjacently disposed rigid portions 91, 93 of tube 32 and is relieved with a

single, axially elongated slot 94 disposed in the tube walls 96. The material 98 that circumferentially bounds slot 94 forms an axially extending leaf spring that interconnects rigid regions 91, 93.” (col. 7, lines 32-40). Considered together with the drawings, it appears that Lucey et al. provides this area of flexibility so that the inner tube 34 can traverse the bend of the stationary tube.

Even of one of ordinary skill in the art had been motivated to combine Lucey et al. and Shutt et al., such a person would not have been motivated to provide a through-slot on the proximal side of element 14 of Lucey et al. since there would be no need for flexibility at such a location. Nor would there have been any motivation for one of ordinary skill in the art to provide a through-slot instead of the notch shown around reference number 209 in Shutt et al. Accordingly, claims 1-4 are patentable over Lucey et al. in view of Shutt et al.

In addition, with respect to claims 2 and 4, in Lucey et al. the slot 94 is spaced from element 24; there does not appear to be a way of assembling the device so that any portion of element 24 is received within the slot 94.

Claims 5-6 and 11

The rejection of claims 5-6 and 11 under 35 USC §103(a) as being unpatentable over Steadman et al. in view of Troutner et al. is respectfully traversed.

The characterization of the lower portion of housing 21 of Steadman et al. as the support portion of the actuator module is respectfully traversed. If the housing 21 of Steadman et al. is considered to constitute parts of both the actuator module and tool module, then it does not appear that the these components could be assembled and disassembled so that at least one of the modules could be reused independent of the other module. In addition, such a construction would not have a tool module that is discrete from the actuator module.

The characterization of the lower portion of housing 21 of Steadman et al. as the hollow elongate support member is respectfully traversed. If part of the housing 21 constitutes the elongate support member, it does not appear that it could also be fixed to the distal end of the housing and could not extend outwardly from the housing.

In addition, Steadman et al. teaches that “the driver assembly is able to produce countering forces on the surgical device when desired. For example, the driver assembly is capable of providing a force greater than that which is provided by the operator such that one gentle squeeze of the trigger arm translates into a forceful push of the needle. This enables the operator to penetrate hard tissue or cartilage with the needle with ease. Alternatively, the driver is able to produce a force less than that provided by the operator. In this case, one squeeze of the trigger arm produces a gentle push of the needle thereby enabling the operator to perform delicate puncturing of soft tissue with significantly reduced chance of error which minimizes patient trauma.” (col. 2, lines 44-56). To translate a gentle squeeze of the trigger into a greater force, Steadman et al. use a system of springs and lever arms (see col. 11, lines 1-8). Given that Steadman et al. teaches that the desired forces can be achieved with the mechanical structures shown, what would have motivated one of ordinary skill in the art to change the Steadman et al. devices to use a power pack instead? Without adding the power pack, what advantage would there be to modifying Steadman et al. to produce a modular device?

Absent motivation to combine references, a rejection under 35 USC 103 is not appropriate. Accordingly, claims 5-6 and 11 are patentable over Steadman et al. in view of Troutner et al.

Claim 7

The rejection of claim 7 under 35 USC §103(a) as being unpatentable over Steadman et al. in view of Matthews et al. is respectfully traversed.

First, as indicated above, the lower portion of housing 21 of Steadman et al. cannot constitute part of both the actuator module and the discrete tool module, and cannot serve as the support portion of the actuator module while also serving as the housing and the elongate support member: other claim elements cannot be met if the lower portion of housing 21 of Steadman et al. is so characterized. Even if one of ordinary skill would have been motivated to combine the teachings of Steadman et al. and Matthews et al., that person would still not have achieved the invention claimed in claim 7.

Claim 9

The rejection of claim 9 under 35 USC §103(a) as being unpatentable over Steadman et al. in view of Matthews et al. and Burbank et al. is respectfully traversed.

First, as indicated above with respect to claims 5 and 7, the lower portion of housing 21 of Steadman et al. cannot constitute part of both the actuator module and the discrete tool module, and cannot serve as the support portion of the actuator module while also serving as the housing and the elongate support member of the discrete tool module: other claim elements cannot be met if the lower portion of housing 21 of Steadman et al. is so characterized. For example, how can the housing 21 of Steadman et al. be fixed to itself and extend outwardly from itself?

Claims 12-15

The rejection of claims 12-15 under 35 USC §103(a) as being unpatentable over Steadman et al. in view of Shutt et al. is respectfully traversed.

First, as indicated above with respect to claims 5 and 7, the lower portion of housing 21 of Steadman et al. cannot constitute part of both the actuator module (the support portion) and the discrete tool module (the hollow housing), and cannot serve as the support portion of the actuator module while also serving as the housing and the elongate support member of the discrete tool module: other claim elements cannot be met if the lower portion of housing 21 of Steadman et al. is so characterized. For example, if the housing 21 of Steadman et al. is part of the actuator module, how can it also be part of the tool module that is a separate element of a kit?

Secondly, the characterization of Steadman et al. is further traversed in that it is not seen that the Steadman et al. housing 21 of FIG. 2A is connected to the cannular 128 of FIG. 12. FIGS. 2A and FIG. 12 appear to illustrate different embodiments of the Steadman et al. invention.

In addition, even if one of ordinary skill in the art were to combine Steadman et al. with Shutt et al., the invention of claims 12-15 would not necessarily result. The structure shown in FIG. 11 of Shutt et al. does not have all the discrete components of the tool module of claim 5.

Claim 21

The rejection of claim 21 under 35 USC §103(a) as being unpatentable over Shutt et al. in view of Matthews et al. and Burbank et al. is respectfully traversed.

First, as indicated above with respect to claims 5, 7 and 12-15, the lower portion of housing 21 of Steadman et al. cannot constitute part of both the actuator module (the support portion) and the discrete tool module (the hollow housing), and cannot serve as the support portion of the actuator module while also serving as the housing and the elongate support

member of the discrete tool module: other claim elements cannot be met if the lower portion of housing 21 of Steadman et al. is so characterized. For example, if the housing 21 of Steadman et al. is part of the actuator module, how can it also be part of the tool module that is a separate element of a kit?

Claims 22-24

The rejection of claims 22-24 under 35 USC §103(a) as being unpatentable over Shutt et al. in view of Matthews et al. is respectfully traversed. Neither Shutt et al. nor Matthews et al. is seen to disclose a surgical instrument wherein elongate substantially flexible distance references have beveled distal ends. To the contrary, Matthews et al. would suggest rounded distal ends for the measuring ends of wires (see, e.g. claim 24, col. 10, lines 3-4).

CONCLUSION

In view of the above, it is believed that all of claims 1-7, 9, 11-19 and 21-24 are in condition for allowance. Reconsideration and reexamination of all of claims 1-7, 9, 11-19 and 21-14 is respectfully requested. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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